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W81XWH-08-1-0429

TITLE:
CARESS: Couples' Arousal Relationship Satisfaction Survey

PRINCIPAL INVESTIGATOR:
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Dr. Thomas Polascik (Duke)

CONTRACTING ORGANIZATION:
University of Virginia

Charlottesville, VA 22908

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14. ABSTRACT

Purpose: The purpose of the study is to assess psychosocial factors (anxiety, depression, body image, fear of recurrence, arousal, libido, erection) simultaneously at an individual level to determine which has the greatest influence on couples' satisfaction. We believe that by identifying patterns of psychosocial adaptation associated with poor relationship satisfaction, we can target couples at risk for significant relationship stress. Through adjusting expectations, psychosocial education, and couples' counseling as necessary, we can improve the HRQOL enjoyed by PCa survivors and their partners.

Progress-To-Date: Dr. Krupski's transfer to UVA necessitated a transfer of the grant and IRB approval from UVA as well as amended IRB approval at Duke. This ended up being a tedious process. The grant was transferred from Duke to UVA on January 23, 2010. We then had to negotiate a subcontract to Duke, this was approved by DOD on The fully executed modification of the basic award and transfer to Contract Specialist is **Mr. Christopher Baker**, christopher.l.baker@amedd.army.mil, 301-619-2332 occurred May 14, 2010. We then had to arrange a subcontract between Duke and UVA. This was sent from UVA to Duke until August 6, 2010 and not finalized at Duke until November of 2010. This delay occurred because Vladimir Mouraviev transferred institutions and Dr. Polascik's effort was adjusted to compensate.

The first focus group was held on Jan 14th 2011. The moderators met with 4 couples as 1 couple cancelled at the last minute due to weather. The patients met in one room and the partners in another. They spoke as a group for 2 hours. The audio recordings are currently being transcribed. We have identified the need to "back up" couples now that we experienced a last minute cancellation. We also had some difficulty amplifying the Snowball recording via Camtasia studio program. These details appear to be ironed out now. The second focus group is tentatively scheduled for February 25th 2011.

Results and Significance: An abstract was submitted to the 2011 IMPaCT Conference sponsored by CDMRP CURES scheduled for March 2011. Dr. Krupski will be in attendance and hopefully have focus group data to share with the participants during the poster session March 9th.

Table of Contents

Introduction	6
Body	6
Key Research Accomplishments	7
Reportable Outcomes	7
Conclusion	Error! Bookmark not defined.
References	8
Appendices	8

Introduction

Few, if any, researchers have attempted to tackle the ambitious task of integrating the psychological literature with the sexual functioning literature. We propose assessing psychosocial factors (anxiety, depression, body image, fear of recurrence, arousal, libido, erection) simultaneously at an individual level to determine which has the greatest influence on couples' satisfaction. We believe that by identifying patterns of psychosocial adaptation associated with poor relationship satisfaction, we can target couples at risk for significant relationship stress. Through adjusting expectations, psychosocial education, and couples' counseling as necessary, we can improve the HRQOL enjoyed by PCa survivors and their partners. Relative to this broad objective, the specific aims of this study are to:

1. *Phase I: Identify draft items that capture the symptoms and effects most important to the patient and partner in terms of relationship satisfaction (DUHS)*
 - a. After literature review of existing items, allow focus groups consisting of patient and partner to prioritize, develop, and modify items.
 - b. Perform cognitive testing on draft items to ensure conceptual validity.
2. *Phase II: Validation testing of proposed items (DUHS)*
 - a. Devise a battery of validated instruments measuring constructs expected to correlate and discriminate between proposed sexual function domains
 - b. Administer validated instruments and proposed sexual function items to patients-partners
3. *Phase III: Use those results to determine the psychometrics of the instrument (UVA and DUHS)*
 - a. Evaluation of latent structure
 - b. Reliability testing (test-retest, internal consistency)
 - c. Construct validation

Body

We will list our accomplishments as per the revised statement of work.

Months 1-3

Task 1

REGULATORY and CONTRACTING

Regulatory process through UVA IRB, Duke IRB, and Dept. of Defense **Complete**

The subcontract from UVA to Duke was not finalized until November 2010. We are finally up and running.

Months 3-7

Task 2

RECRUITMENT PROCESS-participants

Mail introductory letters to Duke longitudinal database members with contact information. **Initiated and Ongoing**

Task 3

Post flyers in Duke Prostate Center and Duke Urology clinics **Initiated and Ongoing**

Task 4

Conduct phone interviews for eligibility criteria and consent. Goal is 20 men and women for focus groups. This process is ongoing for focus group participants and repository for cognitive testing and validation. **Initiated and Ongoing**

Task 5

RECRUITMENT PROCESS-controls

We are currently keeping track of men seen in the clinic by Drs. Krupski and Polascik for conditions that are unrelated to the prostate. Ideally, these will be benign hematuria work ups and not end stage cancers for

example. This database will be used to generate letters to healthy controls as we get closer to Phase III.

Initiated and Ongoing

Months 7- 16

FOCUS GROUP

The first focus group occurred on January 14, 2011 and consisted of 4 couples. The fifth couple cancelled due to concerns over the weather. In terms of treatment options, 3 men had surgery and 1 had radiation. All completed the demographics survey and consent. The moderator session with Dr. Polascik interviewing the men and Dr. Krupski interviewing the women lasted 2 hours. We had a few small glitches in the process. First, we identified that the SNOWBALL recording device required special software. Luckily, we were able to download a 30 day trial package of Camtasia Audio studio. The partner audio was successfully recorded through the snowball and audio amplified with Camtasia. However, the patient audio recorded through the computer microphone rather than the snowball for unclear reasons. We will trouble shoot this before the next focus group. Both transcript have been completed and will be sent to Dr. Maliski. **Initiated and Ongoing**

Task 6

RECRUITMENT Hurdles

We need to hold 3 more focus groups. We learned from our first encounter that we should have a back up couple to call in. We are having trouble identifying a day of the week that the other couples can attend. Several couples can come only on Friday which necessitates rearranging Dr. Polascik's operating room schedule and cancelling Dr. Krupski's clinic. Another strategy we are employing to get couples in is to schedule around their follow up appointment in Durham. If this does not work, we may try to interview the partners and patients on different days. Lastly, we need to ensure we are sampling from the radiation patient database. For diversity, 2 of the focus group will be predominantly white men while 1 will be predominantly AA men. We are trying to schedule the AA men currently. **Initiated and Ongoing**

According to the revised timeline, we are approximately 3 months behind. If we hold the focus groups in close proximity to each other, we should be able to re-establish the timeline.

Key Research Accomplishments

Data has not yet been obtained.

Reportable Outcomes and Conclusion

Data has not yet been obtained.

References

None

Appendices

1. Original SOW (Statement of Work)- include because the timeline of this annual report (July 2009- January 2011) encompasses the grant and subcontract transfer
2. Updated SOW

Name: Tracey L. Krupski

Title: CARESS (Couples' Arousal Relationship Satisfaction Survey) Statement of Work

(ORIGINAL)

We propose assessing psychosocial factors (anxiety, depression, body image, fear of recurrence, arousal, libido, erection) simultaneously at an individual level to determine which has the greatest influence on couples' satisfaction. We anticipate that the variables predictive of a quality relationship will vary between males and females. We believe that identification of patterns of psychosocial adaptation associated with poor relationship satisfaction, we can target couples at risk for significant relationship stress after prostate cancer diagnosis and treatment. Through adjusting expectations, psychosocial education, and couples' counseling as necessary, we can improve the HRQOL enjoyed by prostate cancer survivors and their partners.

Award initiated July 1, 2008

Months 1-3

Year 1

Task 1 Regulatory process through Duke IRB and Dept. of Defense

Months 3-7

Task 2 Mail introductory letters to Duke longitudinal database members with contact information.

Task 3 Post flyers in Duke Prostate Center and Duke Urology clinics

Task 4 Conduct phone interviews for eligibility criteria and consent.

Goal is 20 men and women for focus groups. This process is ongoing for repository for cognitive testing and validation.

Task 5 Simultaneously, healthy controls seen by Drs Krupski and Polascik will be targeted as healthy controls with a similar letter. They will be put into the repository.

Months 7-9

Task 6 5 men will be interviewed by Dr. Polascik on the same night as Dr. Krupski interviews 5 women in Duke Cancer center. Parking will be provided and \$50 incentive paid to each couple. This will occur on 4 separate occasions. For diversity, 2 of the focus group will be predominantly white men while 1 will be predominantly AA men. The final group will be mixed race. All sessions will be recorded. All focus groups will be done in a 6 week period to ensure consistency on the part of the moderators.

Months 9-12

Task 7 Transcription of all the tapes will be performed.

Task 8 Dr. Maliski will qualitatively analyze the tapes.

Task 9 Themes will be developed.

YEAR 2

Months 13-16

Task 10 The team will create items for testing.

Task 11 5-7 couples will be interviewed by some combination of Drs. Polascik, Maliski, Krupski and Hoyle in 1:1 interviews. These couples will give their interpretation of the items.

Task 12 The team will assess the clarity of the questions and revise as needed.

Months 16-19

- Task 13 The team will finalize the items into domains.
Task 14 Based on domains, corresponding instruments for convergent and divergent validity will be identified. (potential instruments included in protocol)

Months 20-26

- Task 15 The repository of prostate cancer men and significant others as well as healthy controls (and partners) will be mailed the battery of instruments, letter of explanation, and self addressed stamped envelope.
Task 16 As the questionnaires are returned, the responses will be entered into the database.

Months 26-31

- Task 17 Statistical analysis and psychometric testing.
Task 18 We anticipate some additional mailings may be needed depending on response rate.

Months 30-33

- Task 19 Development of Finalized CARESS instrument.

Months 34-36

- Task 20 Manuscript preparation. (Several)
Task 21 Submission to various journals.

Name: Tracey L. Krupski

**Title: CARESS (Couples' Arousal RELationship Satisfaction Survey) Statement of Work
(Revised)**

We propose assessing psychosocial factors (anxiety, depression, body image, fear of recurrence, arousal, libido, erection) simultaneously at an individual level to determine which has the greatest influence on couples' satisfaction. We anticipate that the variables predictive of a quality relationship will vary between males and females. We believe that identification of patterns of psychosocial adaptation associated with poor relationship satisfaction, we can target couples at risk for significant relationship stress after prostate cancer diagnosis and treatment. Through adjusting expectations, psychosocial education, and couples' counseling as necessary, we can improve the HRQOL (health related quality of life) enjoyed by prostate cancer survivors and their partners.

Award initiated July 15, 2009

Note: All activities will take place at Duke unless otherwise noted

Months 1-3

Task 1 Regulatory process through Duke IRB and Dept. of Defense Complete

Months 3-7

Task 2 Mail introductory letters to Duke longitudinal database members with contact information. Complete

Task 3 Post flyers in Duke Prostate Center and Duke Urology clinics

Task 4 Conduct phone interviews for eligibility criteria and consent. Goal is 20 men and women for focus groups. This process is ongoing for repository for cognitive testing and validation. Initiated then put on hold during transfer of award

Task 5 Simultaneously, healthy controls seen by Drs Krupski and Polascik will be targeted as healthy controls with a similar letter. They will be put into the repository. Initiated then put on hold during transfer of award

Months 7- 13

Transfer grant to UVA and update study documents at Duke and UVA to reflect UVA as the new primary study site. Study on hold in interim.

Months 14-16

(resuming activity, some work from previously accomplished tasks will have to be repeated to ensure participants are still eligible with respect to applicable windows of time as specified in the eligibility section of the protocol.)

Task 6 On 4 separate occasions, 5 men will be interviewed by Dr. Polascik on the same night as Dr. Krupski interviews 5 women in Duke Cancer center. Parking will be provided and \$25 incentive paid to each participant. For diversity, 2 of the focus group will be predominantly white men while 1 will be predominantly AA men. The final group will be mixed race. Audio from all sessions will be recorded.

Months 16-19

Task 7 Transcription of all the tapes will be performed.
 Task 8 Dr. Maliski will qualitatively analyze the tapes.
 Task 9 Themes will be developed.

Months 20-23

Task 10 The team will create items for testing.
 Task 11 2-3 couples will be interviewed by some combination of Drs. Polascik, Maliski, Krupski and Hoyle in 1:1 interviews. These couples will give their interpretation of the items.
 Task 12 Assess the clarity of the questions and revise as needed.

Months 23-26

Task 13 The team will finalize the items into domains.
 Task 14 Based on domains, corresponding instruments for convergent and divergent validity will be identified. (potential instruments included in protocol)

* All of the above work will be done at DUKE alone

Months 27-33

Task 15 The repository of prostate cancer men and significant others as well as healthy controls (and partners) will be mailed the battery of instruments, letter of explanation, and self addressed stamped envelope. **(Duke and UVA)**

Task 16 As the questionnaires are returned, the responses will be entered into the database.

Months 33-38

Task 17 Statistical analysis and psychometric testing.
 Task 18 We anticipate some additional mailings may be needed depending on response rate. **(Duke and UVA)**

Months 38-41

Task 19 Development of Finalized CARESS instrument.

Months 42-44

Task 20 Manuscript preparation. (Several) **(Duke and UVA)**
 Task 21 Submission to various journals. **(Duke and UVA)**

Original

Month # key	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
2008	1 2		3 4		5	6	7	8	9	10	11	12
2009	13 14		15 16		17	18	19	20	21	22	23	24
2010	25 26		27 28		29	30	31	32	33	34	35	36
2011	37 38		39 40		41	42	43	44				

Revised

Month # key	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	June
2009	1 2		3 4		5	6	7	8	9	10	11	12
2010	13 14		15 16		17	18	19	20	21	22	23	24
2011	25 26		27 28		29	30	31	32	33	34	35	36
2012	37 38		39 40		41	42	43	44				

